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Comment on the labelling of “carry-over-preservatives” in detergents

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One decisive reason for labelling preservatives on the packages of detergents is to inform (to protect or to warn) sensitized individuals. However, elicitation of a contact allergic reaction is not a yes/no issue, but a threshold concentration issue. The elicitation threshold differs from preservative to preservative and from individual to individual, and it depends on application circumstances, usually being lower on long-term and/or occlusive skin contact, and higher on short-term skin contact like in rinse-off products or detergents.

Based on corresponding investigations, patch test elicitation thresholds have been defined for some preservatives. From this data, so-called ED (elicitation dose) 10-values have been calculated, which describe the thresholds below which only 10% of those sensitized will react with an allergic contact dermatitis. In other words, 90% of those sensitized will tolerate an exposure to their allergen at doses below the ED 10 without any adverse reaction. Models for extrapolation ED 10 values from patch tests to usage scenarios have been developed, but not validated in many substances.

Considering regulatory aspects of labelling, one has to ask the question which part of the sensitized individuals should be protected or warned. If you wish to protect almost 100%, then you would have to declare even traces of every contact allergen because you will always find at least one patient with an extremely high degree of sensitization, i.e. an extremely low elicitation threshold. In the context of life-threatening immediate-type allergies, this may make sense, but in case of allergic contact dermatitis, this “over-protection” will lead to unnecessary restrictions for most of the allergic patients, considerably narrowing their choice of products and lowering their quality of life.

Against this background, it seems reasonable to define the group of sensitized individuals to be protected first, before deciding on concentration thresholds above which a preservative has to be labelled on pack. Which percentage of those sensitized do we want to protect? 90%? 95%?

Additionally, there is another important, albeit more psychological, aspect of labelling extremely low concentrations of allergens in household products: The longer the list of ingredients on the label, the less the consumer will read it (in full). And if a sensitized person experiences that she or he tolerates a product containing their allergen – which will happen in many cases if allergens present at very low concentrations have to be labelled – then the warning will be ignored on the long run. In other words: This over-labelling counteracts the warning function of (allergen) labelling.

The Information Network of Departments of Dermatology (IVDK) holds the world’s largest clinical database on contact allergy. Former analyses of contact sensitization among professional cleaners did not reveal any increased incidence of contact allergy to preservatives in this group [Liskowsky et al., *Contact Dermatitis* 2011; 65:159-166]. A recent in-depth analysis of contact sensitization to benzisothiazolinone (BIT), which has been submitted to ECHA in the course of the public consultation on “Harmonised Classification and Labelling of Benzisothiazolinone (CAS 2634-33-5)” in May 2021, revealed that there is no increased risk of BIT sensitization for cleaners, and also no evidence that household products pose a corresponding risk. Therefore, from our point of view, there is no allergological need for lower preservative declaration thresholds in detergents.

Considering the above-mentioned issues, thresholds for labelling sensitizing preservatives (EUH208) given in the CLP seem sufficient from the dermato-allergological point of view. The International Association for Soaps, Detergents and Maintenance Products, A.I.S.E., made a proposal with even more conservative on-pack declaration threshold values for several potentially sensitizing and non-sensitizing preservatives in November 2021 (see next page). Under allergological aspects, there is no need to label preservatives present at concentrations below these proposed levels on detergents.

I have expressed a similar opinion concerning the proposed lowering of the threshold for the warning 'contains formaldehyde' (SCCS Opinion SCCS/1632/21 of 7 May 2021). My corresponding statement (Comment on SCCS Opinion SCCS/1632/21) is available on the IVDK website at <https://ivdk.org/en/>.

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Conflicts of Interests:

I don't have any personal conflicts of interests. The IVDK, maintained by the IVDK e.V., of which I am an employee, is sponsored by the chemical, cosmetic and fragrance industry (associations) as well as by public funds. For details, see <http://ivdk.org/en/sponsors/>.

A.I.S.E. PROPOSALS FOR LABELLING OF PRESERVATIVES IN THE DETERGENT REGULATION

FOR PRESERVATIVES THAT ARE SENSITIZERS

Preservative	On-pack declaration threshold	Threshold below which ingredient no longer has a preservation function, even considering synergy with other preservatives	Threshold for EUH208 under CLP (Ref CLP Annex I table 3.4.6)
Glutaraldehyde (Glutaral)	100 ppm	500 ppm	100 ppm
Benzisothiazolinone (BIT)	15 ppm	15 ppm	50 ppm
Methylisothiazolinone (MIT)	1.5 ppm	12.5 ppm	1.5 ppm
Methylchloroisothiazolinone/ Methylisothiazolinone 3:1 (CIT/MIT 3:1)	1.5 ppm	3 ppm	1.5 ppm
Octylisothiazolinone (OIT)	1.5 ppm	4.5 ppm	1.5 ppm
3-Iodo-2-PropynylButylCarbamate (IPBC)	10 ppm	10 ppm	100 ppm
DMDM Hydantoin (DMDMH)	100 ppm	500 ppm	under discussion ¹

FOR PRESERVATIVES THAT ARE NOT CLASSIFIED AS SKIN SENSITIZERS

A general fall-back margin for non-sensitizing ingredients is set at 100 ppm (**this is a conservative value**. To be treated as a default, and assumes the value for skin sensitizer CAT 1A, although the ingredient has no data identifying it as a skin sensitizer).

Preservative	On-pack declaration threshold	Threshold below which ingredient no longer has a technical function, even considering synergy with other preservatives
Potassium sorbate, sorbic acid	100 ppm	1000 ppm
Sodium benzoate, benzoic acid	100 ppm	1000 ppm
Phenoxy ethanol (POE)	100 ppm	2000 ppm
2-Bromo-2-Nitropropane-1,3-diol (Bronopol)	10 ppm	10 ppm
o-Phenylphenol, Sodium o-phenylphenate and Potassium o-phenylphenate	100 ppm	750 ppm
Formic Acid	100 ppm	600 ppm
Dimethylol Glycol	100 ppm	500 ppm
Didecyldimonium Chloride	100 ppm	500 ppm
Lactic Acid	100 ppm	30000 ppm
Sodium Pyrithione	100 ppm	200 ppm

¹ <https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/34913>